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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/962,094	10/31/97	BILLING-MEDEL	P 5995.US.P1

HM22/0708

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EXAMINER	
ARTHUR, L	
ART UNIT	**PAPER NUMBER**
1655	12

DATE MAILED: 07/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/962,094	Billings-Medel et al.
Examiner	**Group Art Unit**
Lisa Athur	1655

[X] Responsive to communication(s) filed on *Apr 26, 1999*.

[ ] This action is **FINAL**.

[ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

[X] Claim(s) *1-39* is/are pending in the application.

Of the above, claim(s) *17-29, 31, 32, 34, 36, and 37* is/are withdrawn from consideration.

[ ] Claim(s) _____ is/are allowed.

[X] Claim(s) *1-16, 30, 33, 35, 38, and 39* is/are rejected.

[ ] Claim(s) _____ is/are objected to.

[ ] Claims _____ are subject to restriction or election requirement.

Application Papers

[ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ]approved [ ]disapproved.

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [ ] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____.

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

[X] Notice of References Cited, PTO-892

[X] Information Disclosure Statement(s), PTO-1449, Paper No(s). *4,8,10*

[ ] Interview Summary, PTO-413

[ ] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election of Group I in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 11-16 are being added to Group I because the polynucleotides drawn to in these claims appears to be the same polynucleotides as those being detected in the method of claim 1.

Therefore, this action includes an examination of Claims 1-16, 30,33,35,38 and 39.

3. Claims 14 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 30 is drawn to polynucleotides which encode at least one "epitope of BS106". The specification does not provide sufficient guidance to enable the skilled artisan to make and use a polynucleotide encoding an epitope of "BS106. The specification teaches a particular sequence from within a known EST which is abundant in breast tissue while being absent from non-breast tissue (page 50, lines 16-19). However, the specification provides no teachings that the polynucleotides of SEQ ID nos 1-4 or the peptide of SEQ ID NO 5 encode an epitope. Selective expression of a nucleotide sequence in breast cells can not be extrapolated to the presence of an epitope because (1) an epitope is a specific sequence recognized by an antibody that is identified

by its functionality. The specification has not provided ány teachings showing that the claimed polynucleotides encode a peptide which contains an epitope which is selectively recognized by an antibody in breast tissue. The specification instead teaches general teaches on how to make and use antibodies which are generated from a peptide synthesized from the disclosed polynucleotides.

The second reason that the presence of an epitope in SEQ ID NO 1-5 is not predictable from the polynucleotide sequence alone that an epitope is not necessarily a linear sequence of nucleotides but can instead be several non-contiguous nucleotides which have proximity due to the three dimensional conformation of the native protein. The sequence of SEQ ID NOs 1-5 is a partial sequence of a protein and would not be expected to fold into the same three dimensional confirmation as it assumes in the native protein in the environment of added amino acids. Furthermore, in order for a sequence to be an epitope, the sequence must be one which is located on the surface of the native protein so that it is accessible to binding by an antibody. The specification does not provide guidance to the skilled artisan to ascertain the location or three dimensional conformation that the disclosed sequence or the native full-length protein would assume. The ability of a peptide having the sequence of SEQ ID NO 5 to stimulate the production of binding antibodies would not allow the skilled artisan to reasonably predict that these same antibodies would have been produced upon immunization with the native protein. Consequently, for all of these reasons, undue experimentation would have been required to a polynucleotide containing an epitope of BS106 since none have been identified.

4. Claims 1-16, 30,33,35,38,39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-16,30,33,35,38,39 are indefinite over the recitation of "target BS106 polynucleotide" because the metes and bounds of this term are unclear. The specification has defined "BS106" as being a particular nucleotide sequence and consequently, the specific identity of a target BS106 polynucleotide is unclear. That is, from the specification and the claims it is unclear as to whether BS106 is SEQ IS NOs 1-5 or a polynucleotide with at least 50% sequence identity to SEQ ID NO 1-5.

B) Claims 1-16,33,35,38,39 are also indefinite over the recitation of "at least 50% identity" because this term makes the claims unclear as to the metes and bounds of a "BS106 specific polynucleotide". The use of "% identity" makes the claims unclear because the polynucleotides which would be encompassed 50% identical to BS106 varies depending upon the particular sequence alignment program and specific parameters used to determine % identity. Neither the specification nor the claims define these parameters, such as on page 11-12 where % identity is discussed.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11-16,33,38,39 rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al.(genbank accession no AA340069, from Nature 377(6547 Suppl.) 3-174 (1995)) and by Hillier et al. (Accession no. R75793, 1995)

Adams et al. Teach a 229 base pair expressed tag sequence (EST), i.e. a polynucleotide, which is about 90% identical to SEQ ID NO 1-5 of this application. (See attachment 1)

Hillier et al. Teach a 403 nucleotide EST containing clone which has 87.9%-95% sequence similarity with SEQ ID NO 1-5 of this application isolated from a human breast cDNA library (cells transfected with a vector containing the EST). (see attachment 1)

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-10, 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis et al. In view of Adams et al. and Hillier et al.

Mullis et al. Teach methods for detecting the presence of a target polynucleotide by contacting a test sample with a target specific probe and detecting target and teaches detection by amplification using specific primers. Mullis et al. also teaches kits containing probes and primers and reagents for hybridization and amplification analysis.

Mullis et al. does not teach a polynucleotide of SEQ ID NOs 1-5 or a polynucleotide with at least 50% identity to SEQ ID NOS 1-5.

However, Adams et al. Teach a 229 base pair expressed tag sequence (EST), i.e. a polynucleotide, which is about 90% identical to SEQ ID NO 1 of this application. Hillier et al. Teach a 403 nucleotide EST containing clone which has 87.9% sequence similarity with SEQ ID NO 1 of this application isolated from A HUMAN BREAST cDNA library (cells transfected with a vector containing the EST).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included the polynucleotides of Adams et al. And Hillier et al. To the methods and kits of Mullis et al. In order to make the claimed invention as a whole. The skilled artisan would have been motivated to have detected the polynucleotides of Adams and Hillier et al. Using the methods of Mullis et al. Because Adams et al. And Hillier et al. Identified

these polynucleotides as encoding expressed sequences in humans which could be used for DNA fingerprinting of individuals.

9. No claims are allowable over the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Lisa B. Arthur

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

July 6, 1999